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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,346

04/15/2005

Stefan Frahling

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

09/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/531,346	Applicant(s) FRAHLING ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1,4-6,10,15-20,23 and 25-31.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicants' entered amendments cancelling claim 24 are sufficient to render moot the new matter rejection previously raised made under the first paragraph of 35 USC 112.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments with regard to the rejection of claims 1, 4-6, 10, 15-20, 23 and 25-27 under 35 USC 103(a) as being unpatentable over the combined teachings of Zecchino et al. and Kojima et al. have been fully considered but they are not persuasive.

The crux of Applicants' argument pertaining to Zecchino is that the reference differs not only dimensionally (e.g., volumetric/geometric dimensions), but also in the specific dissolution behavior and the mode of application of the dissolved article, which is then applied in the form of a solution or gel.

In response, the Examiner respectfully maintains that Applicants' arguments are unpersuasive, primarily because Applicants' have provided no evidence which would remotely suggest that the volume, geometry or proportions of the finished article in anyway impact the usability of said product, beyond it being more aesthetically pleasing to have a sphere shape. Concerning Applicants' assertions that Zecchino is drawn only to membranes, it is respectfully pointed out that Applicants acknowledge Zecchino's teaching of block shaped articles (i.e., 3-dimensional shapes). The Examiner does acknowledge that the reference teaches the resulting shapes as having an upper-limit thickness of 1.5 mm. However, what Applicants do not readily acknowledge is that this thickness is achieved following the division of a larger freeze-dried mass. It is also further pointed out that desired sizes and shapes are achievable by cutting the dried block (col. 3, lines 39-56).

Applicants' remarks concerning the inclusion of soluble collagen as an active agent versus a cross-linking agent have been reconsidered, particularly in light of the recited passages in the specification as well as the prior art made of record. Applicants' remarks respectfully remain unpersuasive, most notably for the reasons already made of record (see Final Rejection mailed 29 June 2010).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore maintained and extended to include newly filed claims 28-31. Considering the limitations of claim 30, the Examiner interprets the claim as setting forth compositional limits to the freeze-dried form which exhibit the recited density and viscosity properties. The composition used in the claimed method is recited as comprising at least 10 wt% of one or more skeleton-forming agents (e.g., Zecchino, Ex. 2, 48 wt% sodium alginate), between 0.000001 (~0 wt%) up to 50 wt% of at least one active agent (e.g., Zecchino, Ex. 2 and claim 5, 1 wt% soluble collagen), 0.1-70 wt% of one or more auxiliary substances (e.g., the remaining 51% of the formulation), and up to 20 wt% of water (e.g., Ex. 2 contains no water). Furthermore, in light of the teaching of collagen as an active agent for the formulations (e.g., Examples, claim 5), it would have been well within the purview of the ordinarily skilled artisan given the teachings of the references, to substitute one active ingredient for another, absent a clear showing of evidence to the contrary. Concerning the remaining claims 28, 29 and 31, the Examiner respectfully maintains, for the reasons discussed above and already made of record, that the combined teachings of Zecchino and Kojima teach the formation of shaped (e.g., 3D) articles which maybe be further shaped and dimensioned as desired (i.e., sliced per Zecchino or spherical per Fig. 6F of Kojima) by the artisan of ordinary skill. That the person using the article would prefer a sphere-shaped article is not enough evidence to convey that the shape lends criticality to the invention.